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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/300,482	04/28/1999	NORDINE CHEIKH	04983.0031.U	4511

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EXAMINER	
MORAN, MARJORIE A	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/300,482	CHEIKH ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-13,15-22,24 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-13,15-22,24 and 27-31* is/are rejected.

7)☒ Claim(s) *27 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

All rejections and objections not reiterated below are hereby withdrawn. Claims 1, 11-13, 15-22, 24, and 27-31 are pending.

Claim Objections

Claims 27 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 27 and 29 depend, respectively, from claims 26 and 10, which are cancelled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 11-13, 15-22, 24, and 27-31 are again rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.
The arguments filed 3/2/05 have been fully considered but are not persuasive. Applicant's arguments with regard to uses of the claimed nucleic acids to identify polymorphisms, as molecular markers and probes, to identify homologs, in microarrays, and to transform plants have been previously addressed. For the same reasons as those set forth in at least the Office Actions mailed 4/12/04 and 12/2/04, the examiner maintains that these uses are not specific, substantial and credible for the nucleic acid sequences recited in the instant claims.

In response to the repeated argument that the claimed sequences encode phosphogluconate pathway enzymes, it is again noted and maintained, as previously set forth

and maintained in previous office actions, that the specification does not actually disclose that any of the claimed SEQ ID NO's is known to encode a protein or peptide, specifically one of the enzymes recited in the claims. For the nucleic acid to have utility based on a putatively encoded peptide, the identity and activity of the peptide must be known or established. In response to the argument that the claims also recite "fragments", thus a complete ORF is not necessary, it is again noted that a fragment of a protein, wherein the fragment itself does not have utility or activity, does not necessarily have a utility.

The examiner has NOT stated that an ORF or knowledge of an appropriate ATG codon is necessary. However, where the utility of a nucleic acid sequence rests on the utility of an encoded protein, knowledge of an ORF or appropriate ATG would aid one skilled in the art to determine what, if any peptide may be expressed by a particular nucleic acid sequence. In fact, as previously set forth, and despite applicant's arguments to the contrary, it is not known for ANY of the claimed sequences what the ORF is, or whether any sequence is actually translated into a peptide, or, if translated, what the activity or function of that peptide may be. For example, SEQ ID NO: 14 comprises six "ATG" codons, but it is not known which, if any, is the start codon for a 6-phosphogluconate dehydrogenase. As set forth in the office action of 12/20/00, none of the claimed SEQ ID NO's appears to be long enough to encode the entirety of the enzyme disclosed by the specification to be putatively encoded thereby. It is possible that a claimed SEQ ID NO: encodes a fragment of an enzyme; however, it is not in fact disclosed whether that fragment has activity or another function such that the fragment has utility under 35 USC 101. In response to the argument that fragments may be used as probes, it is noted that a "probe" (i.e. for a homologous sequence) for a sequence of unknown function does not impute utility to the probe itself. There is no evidence in the instant specification, and none has been filed to show or support that any of the claimed nucleic acids do, in fact, encode ANY

peptide, specifically one with enzymatic activity. In response to the argument that the examiner has "admitted" that the specification discloses that the nucleic acids encode enzymes, it is noted that the totality of the examiner's statements indicate that while Table A indicates a relationship between the claimed sequences and enzymes known in the art, the specification does not, in fact, teach that the claimed nucleic acid sequences are known to actually encode ANY protein or peptide, specifically those set forth in Table A.

In response to the argument that the claims do not recite enzymes, it is noted that claims 1 and 24 so, in fact, recite nucleic acids which encode enzymes. The examiner agrees with applicant that the claims are directed to nucleic acids. A nucleic acid may have utility if it encodes a polypeptide with either a well-established or a specific, substantial and credible utility. Enzymes with a known activity are generally regarded as having a well-established utility. Thus, the instantly claimed nucleic acids MAY have utility if they do, in fact, encode enzymes; hence the analysis of the claims with regard to encoded enzymes. However, the specification does not disclose, and no evidence has been filed, to establish that the claimed nucleic acids, in fact, encode enzymes or any other polypeptide with a known activity or identity such that a utility may be ascribed to the encoding nucleic acids.

For all the reasons previously set forth and set forth above, the rejection is maintained.

Claims 1, 11-13, 15-22, 24, and 27-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. As the utility rejection is maintained, so is the enablement rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 22, 24 and 28 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

Applicant's arguments filed 3/2/05 repeat those previously set forth. They have been fully considered, but are not persuasive for the reasons set forth in the previous office action, thus the rejection is maintained.

35 U.S.C. 112, Written Description Rejection

Claims 1, 11-13, 15-22, 24, and 27-30 are again rejected, as previously set forth in multiple office actions, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed 3/2/05 have been fully considered but they are not persuasive. Applicant's arguments are addressed below.

The specification discloses SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619. which putatively encode various phosphogluconate pathway enzymes. Sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 meet the written description

provisions of 35 USC 112, first paragraph. However, claims 1, 2, 10-22, 24-30 recite open claim language (comprising) and claims 1, 22, 24 and 28 are specifically directed to encompass sequences that encode a variety of enzymes. As the sequences recited in the claims are apparently fragments which do not appear to comprise ORF's or actually encode any known proteins, a nucleic acid "comprising" the fragments encompasses much larger sequences which may encode entirely different proteins from those recited, encompasses genomic sequences which may also comprise introns, noncoding regions, etc.

Applicant argues the disclosure need only show that applicant was in possession of the claimed inventions, and insists that the instant specification does so. In response, it is noted that the specification does not, in fact, actually describe any nucleic acid KNOWN to encode an entire enzyme, and therefore does not describe nor show possession of the claimed invention of at least claims 1, 22, 24, and 28.

In response to the argument that a representative number of nucleic acids provides a written description basis for a genus thereof, it is noted that a single specific member does not support a genus of the breadth claimed. In particular, a fragment of a putatively encoding nucleic acid reasonably lacks written description for a full-length encoding nucleic acid for the entirety of an enzyme. In response to the argument that the instant sequences define common structural features of a members of a genus to distinguish them from others, it is noted that the specification does not define the instantly claimed sequences as being or having a common structural feature, such that the group claimed, or any individual member thereof, may be distinguished from another "genus" of nucleic acids. Thus, the arguments are not based on the facts set forth in the instant specification, and are not persuasive.

With the exception of sequences consisting of SEQ ID NO's 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, the skilled artisan cannot envision the detailed chemical structure of the

encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. For all of the reasons set forth above and previously set forth, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11, 16, 29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/425,114. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 28,690 of '114 is identical to instant SEQ ID NO: 225, therefore claim 1 of '114 encompasses the subject matter of each of claims 1, 11, 16, 29, and 31.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 11, 16, 29, and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/425,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 155,395 of '115 is identical to instant SEQ ID NO: 225, therefore claim 1 of '115 encompasses the subject matter of each of claims 1, 11, 16, 29, and 31.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
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5/19/05